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EXAMINER

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PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No. 10/588,172	Applicant(s) LAITENBERGER ET AL.	
	Examiner UNSU JUNG	Art Unit 1641	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 27 October 2009.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-29 is/are pending in the application.
- 4a) Of the above claim(s) 27 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-26, 28 and 29 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☒ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 01 August 2006 is/are: a) ☐ accepted or b) ☒ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All b) ☐ Some * c) ☐ None of:
1. ☒ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date <u>8/1/2006</u> . | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Election/Restrictions

1. Applicant's election without traverse of species 1 (sample is returned to the patient) in the reply filed on October 27, 2009 is acknowledged. Claims 1-26, 28, and 29 read on the elected species.

Status of Claims

2. Claims 1-29 are pending, claims 27 have been withdrawn from consideration, and claims 1-26, 28, and 29 are currently under consideration for patentability under 37 CFR 1.104.

Priority

3. Applicant's claim for the benefit of a prior-filed application under 35 U.S.C. 119(e) or under 35 U.S.C. 120, 121, or 365(c) is acknowledged. The instant application is a national phase under 35 U.S.C. 371 of PCT International Application No. PCT/GB2005/000367, filed on February 3, 2005.

Acknowledgment is made of applicant's claim for foreign priority under 35 U.S.C. 119(a)-(d). The certified copies of United Kingdom Patent Application No.'s 0402326.3, filed on February 3, 2004, 0402324.8, filed on February 3, 2004, 0402325.5, filed on March 3, 2004, 0402327.1, filed on February 3, 2004, 0402323.0, filed on February 3, 2004, 0404924.3, filed on March 4, 2004, 0405313.8, filed on March 9,

Art Unit: 1641

2004, 0405312.0, filed on March 9, 2004, and 0408535.3, filed on April 16, 2004 have been filed in the instant application.

Information Disclosure Statement

4. The information disclosure statement (IDS) submitted on August 1, 2006 has been considered by the examiner. The following minor corrections have been made on the signed and initialed copy of the IDS:

- WO 2004/027393A1: Publication date has been corrected to "April 1, 2004";
- Blanco-Lopez et al.: publication date "January 2004" has been inserted; and
- Jakoby et al.: publication year "1999" has been inserted.

Drawings

5. The drawings are objected to as failing to comply with 37 CFR 1.84(p)(5) because they do not include the following reference sign(s) mentioned in the description: 4b (p18, line 11) in Fig. 8. Corrected drawing sheets in compliance with 37 CFR 1.121(d) are required in reply to the Office action to avoid abandonment of the application. Any amended replacement drawing sheet should include all of the figures appearing on the immediate prior version of the sheet, even if only one figure is being amended. Each drawing sheet submitted after the filing date of an application must be labeled in the top margin as either "Replacement Sheet" or "New Sheet" pursuant to 37

Art Unit: 1641

CFR 1.121(d). If the changes are not accepted by the examiner, the applicant will be notified and informed of any required corrective action in the next Office action. The objection to the drawings will not be held in abeyance.

Specification

6. The disclosure is objected to because of the following informalities: U.S. Patent No. on p11, line 30 and p19, line 22 is incorrect as it contains an extra number.

Appropriate correction is required.

Claim Rejections - 35 USC § 102

7. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

8. Claims 1, 23, and 25 are rejected under 35 U.S.C. 102(b) as being anticipated by Williams et al. (U.S. PG Pub. No. US 2003/0053935 A1, Mar. 20, 2003) (hereinafter “Williams”).

The prior art reference, Williams, has been cited in the IDS dated August 1, 2006.

Williams anticipates instant claims by teaching a sensor (see entire document) comprising:

Art Unit: 1641

- a substrate (200 in Fig. 5);
- a confinement structure created from materials applied to the substrate by deposition, wherein the confinement structure comprises at least a first limiting structure defining a first interior surface (91 and 101 in Fig. 5);
- a transducer proximal to the first interior surface (82 in Fig. 5); and
- a first synthetic polymer capable of selectively binding a first analyte within the confinement structure (p3, paragraph [0038]).

With respect to claim 23, the substrate of Williams is substantially planar (Fig. 5).

With respect to claim 25, Williams teaches a method of detecting a target species in a sample by contacting the sensor with a sample suspected of containing the target species (p4, paragraph [0046]).

Claim Rejections - 35 USC § 103

9. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

10. The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.

Art Unit: 1641

2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

11. This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

12. Claims 1-12, 14, 16, 17, and 20-25 are rejected under 35 U.S.C. 103(a) as being unpatentable over Gumbrecht et al. (U.S. Patent No. 5,900,128, May 4, 1999) (hereinafter "Gumbrecht") in view of Blanco-López et al. (*Trends in Analytical Chemistry*, January 2004, Vol. 23, pp36-48) (hereinafter "Blanco-López").

The prior art reference, Blanco-López, has been cited in the IDS dated August 1, 2006.

Gumbrecht teaches an electrochemical sensor provided on a substrate (see entire document). The sensor includes a confinement structure created from materials applied to the substrate (reference numeral 1 in Fig. 1), wherein the confinement structure comprises at least a first limiting structure defining a first interior space and a

Art Unit: 1641

transducer (reference numeral 2 in Fig. 1). The electrochemical sensor of Gumbrecht is not prone to cracking or to fluid leakage which can result in a short circuiting or corrosion of sensor (column 1, lines 40-43).

With respect to claim 2, Gumbrecht teaches a sensor, wherein the confinement structure comprises a second limiting structure defining a second interior space, the second interior space containing the first interior space (Fig. 1).

With respect to claim 3, Gumbrecht teaches a sensor, wherein the confinement structure further comprises one or more further limiting structures defining one or more further interior spaces, the one or more further interior spaces each containing an interior space (Fig. 1).

With respect to claim 10, Gumbrecht teaches a sensor, wherein the limiting structures of the confinement structure are annular (Fig. 2).

With respect to claim 11, Gumbrecht teaches a sensor, wherein the sensor further comprises at least one additional confinement structure and a transducer proximal to the first interior space of each of the at least one additional confinement structures (column 1, lines 50-67).

With respect to claims 16 and 17, Gumbrecht teaches the first and second interior spaces contain a conducting material (electrolyte layer, Abstract and Fig. 1).

With respect to claim 20, Gumbrecht teaches that the transducer is disposed on the substrate (Fig. 1).

With respect to claim 21, Gumbrecht teaches that the transducer is an electrochemical transducer (Abstract).

With respect to claim 22, Gumbrecht teaches that the substrate is a silicon wafer and substantially planar (column 3, lines 8-11 and Fig. 1).

With respect to claim 24, Gumbrecht teaches that the confinement structure is fabricated from a polyimide (Abstract).

However, Gumbrecht fails to teach that the electrochemical sensor further comprises a first synthetic polymer capable of selectively binding a first analyte within the confinement structure.

Blanco-López teaches molecular imprinted polymers (MIPs), which are an important class of synthetic materials mimicking molecular recognition by natural receptors (see entire document, particularly Abstract). MIPs have a great range of applications because of the theoretical lack of restriction on size, shape, or chemical character of the imprinted molecule (p36, 1. *Introduction*, 1st paragraph). The possibility of tailor-made, highly selective artificial receptors at low cost with good mechanical, thermal, and chemical properties make these synthetic materials appear ideal chemoreceptors (p36, 1. *Introduction*, 1st paragraph). For sensing application, MIPs can be immobilized on electrode surface for electrochemical detection (p45, 4.1 *Integration through powder processing*).

With respect to claim 11, Blanco-López teaches that different types of recognition elements can be associated with different sensors (p47, 6.4 *Application to real samples*).

With respect to claims 12 and 14, Blanco-López teaches that the first synthetic polymer is a molecularly imprinted polymer as set forth above.

Art Unit: 1641

With respect to claim 25, Blanco-López teaches a method of detecting a target species in a sample comprising contacting a sensor with a sample containing or suspected to contain the target species (p47, *6.4 Application to real samples*).

Therefore, it would have been prima facie obvious to one of ordinary skill in the art at the time of the invention to incorporate MIPs on the electrochemical sensor surface as taught by Blanco-López in the sensor of Gumbrecht in order to detect analytes using tailor-made, highly selective artificial receptors. The advantage of using synthetic receptors that can be tailor-made to be highly selective artificial receptors at low cost with good mechanical, thermal, and chemical properties with no size, shape, or chemical character restriction provides the motivation to combine teachings of Gumbrecht and Blanco-López. One of ordinary skill in the art would have had a reasonable expectation of success in combining teachings of Gumbrecht and Blanco-López since Blanco-López teaches that MIPs can be incorporated into variety of electrochemical sensors.

With respect to claims 4 and 5, Blanco-López teaches MIPs capable of selectively binding a first analyte is disposed on the sensor surface. Since the sensor is present in the proximity of the first and second interior spaces, which includes electrolyte layer, the MIPs must necessarily be disposed within the first and second interior spaces.

With respect to claims 6-9, Gumbrecht in view of Blanco-López teaches the claimed sensor device except for the internal diameter of the first limiting structure being about 10-350 μm , the height of the first limiting structure being about 1-10 μm , the

Art Unit: 1641

internal diameter of the second limiting structure being about 50-600 μm , and the height of the second limiting structure is about 1- 100 μm . It would have been an obvious matter of design choice to adjust the dimensions (diameter and height) of the first and second limiting structures, since such a modification would have involved a mere change in the size of a component. A change in size is generally recognized as being within the level of ordinary skill in the art. *In re Rose*, 220 F.2d 459, 105 USPQ 237 (CCPA 1955) (Claims directed to a lumber package “of appreciable size and weight requiring handling by a lift truck” where held unpatentable over prior art lumber packages which could be lifted by hand because limitations relating to the size of the package were not sufficient to patentably distinguish over the prior art.); *In re Rinehart*, 531 F.2d 1048, 189 USPQ 143 (CCPA 1976) (“mere scaling up of a prior art process capable of being scaled up, if such were the case, would not establish patentability in a claim to an old process so scaled.” 531 F.2d at 1053, 189 USPQ at 148.). *In Gardner v. TEC Systems, Inc.*, 725 F.2d 1338, 220 USPQ 777 (Fed. Cir. 1984), *cert. denied*, 469 U.S. 830, 225 USPQ 232 (1984), the Federal Circuit held that, where the only difference between the prior art and the claims was a recitation of relative dimensions of the claimed device and a device having the claimed relative dimensions would not perform differently than the prior art device, the claimed device was not patentably distinct from the prior art device.

13. Claims 13, 28, and 29 are rejected under 35 U.S.C. 103(a) as being unpatentable over Gumbrecht (U.S. Patent No. 5,900,128, May 4, 1999) in view of

Art Unit: 1641

Blanco-López (*Trends in Analytical Chemistry*, January 2004, Vol. 23, pp36-48) as applied to claim 1 above, and further in view of Leyland-Jones (U.S. PG Pub. No. US 2003/0053950 A1, Mar. 20, 2003).

Gumbrecht in view of Blanco-López teaches a sensor and method of detecting target species in a sample using the sensor as set forth above.

With respect to claims 28 and 29, Gumbrecht teaches the first and second interior spaces contain a conducting material (electrolyte layer, Abstract and Fig. 1) and the transducer is an electrochemical transducer (Abstract).

Although Gumbrecht in view of Blanco-López teaches that a variety of analytes can be determined by employing MIPs that can be tailor-made to be highly selective artificial receptors at low cost with good mechanical, thermal, and chemical properties, Gumbrecht in view of Blanco-López fails to specifically teach MIPs capable of selectively binding propofol.

Leyland-Jones teaches a method of characterizing multi-determinant metabolic phenotype by detecting metabolites of metabolic pathways in a biological sample from individuals in order to provide individualized treatment regime (p13, paragraphs [0137] and [0141]). Enzymes including CYP2E1 are involved in the metabolism of a large number of drugs and as a result have important implications in the outcome of individual drug treatment regimes (paragraph [0177]). CYP2E1 metabolizes several drugs and dietary constituents including isoflurane, halothane, methoxyflurane, enflurane, propofol, thiamylal, sevoflurane, ethanol, acetone, acetaminophen, nitrosamines, nitrosodimethylamine, and p-nitrophenol (p27, paragraph [0355]).

Therefore, it would have been *prima facie* obvious to one of ordinary skill in the art at the time of the invention to design MIPs of Gumbrecht in view of Blanco-López to specifically detect propofol since Leyland-Jones teaches that propofol is one of the metabolites of CYP2E1 in individuals. The advantage of detecting metabolic pathways in order to provide individualized treatment regimes for patients provides the motivation to combine teachings of Gumbrecht in view of Blanco-López and Leyland-Jones. Further, one of ordinary skill in the art would have had a reasonable expectation of success in combining teachings of Gumbrecht in view of Blanco-López and Leyland-Jones since Blanco-López teaches that MIPs can be tailor-made to be highly selective artificial receptors at low cost with good mechanical, thermal, and chemical properties as set forth above.

14. Claim 15 is rejected under 35 U.S.C. 103(a) as being unpatentable over Gumbrecht (U.S. Patent No. 5,900,128, May 4, 1999) in view of Blanco-López (*Trends in Analytical Chemistry*, January 2004, Vol. 23, pp36-48) as applied to claim 1 above, and further in view of Ulbricht et al. (U.S. Patent No. 6,670,427 B1, Dec. 30, 2003) (hereinafter "Ulbricht").

Gumbrecht in view of Blanco-López teaches a sensor and method of detecting target species in a sample using the sensor as set forth above. Although Gumbrecht in view of Blanco-López teaches a sensor comprising a first synthetic polymer of a molecularly imprinted polymer, Gumbrecht in view of Blanco-López fails to specifically teach that the sensor comprises at least one additional confinement structure having a

Art Unit: 1641

reference material therein and the reference material is a corresponding non-imprinted polymer.

Ulbricht teaches a method of using non-imprinted polymer as a reference sample (see entire document, particularly column 11, Example 5).

Therefore, it would have been *prima facie* obvious to one of ordinary skill in the art at the time of the invention to employ a non-imprinted polymer as taught by Ulbricht in the sensor and method of Gumbrecht in view of Blanco-López in order to provide a reference sample. The advantage of having a reference sample (i.e. negative control) provides the motivation to combine teachings of Gumbrecht in view of Blanco-López and Ulbricht with a reasonable expectation of success since such reference data is necessary to determine specificity of target binding to the first synthetic polymers capable of specifically binding to the target species.

15. Claims 18 and 19 are rejected under 35 U.S.C. 103(a) as being unpatentable over Gumbrecht (U.S. Patent No. 5,900,128, May 4, 1999) in view of Blanco-López (*Trends in Analytical Chemistry*, January 2004, Vol. 23, pp36-48) as applied to claim 1 above, and further in view of Dickert et al. (U.S. Patent No. 6,223,589 B1, May 1, 2001) (hereinafter "Dickert").

Gumbrecht in view of Blanco-López teaches a sensor and method of detecting target species in a sample using the sensor as set forth above. Although Gumbrecht in view of Blanco-López teaches a sensor comprising a first synthetic polymer of a molecularly imprinted polymer, Gumbrecht in view of Blanco-López is silent on teaching

Art Unit: 1641

that at least one confinement structure further comprises one or more additional substances which provide a specific environment such as a non-aqueous environment.

Dickert teaches that molecular imprinting coatings can be used as both gas and liquid sensors (see entire document, particularly column 2, lines 31-37).

Therefore, it would have been *prima facie* obvious to one of ordinary skill in the art at the time of the invention to use the sensor of Gumbrecht in view of Blanco-López for both gas and liquid sensors as taught by Dickert. The advantage of detecting analytes in both gas and liquid phases provide the motivation to teachings of Gumbrecht in view of Blanco-López and Dickert with a reasonable expectation of success.

16. Claim 26 is rejected under 35 U.S.C. 103(a) as being unpatentable over Gumbrecht (U.S. Patent No. 5,900,128, May 4, 1999) in view of Blanco-López (*Trends in Analytical Chemistry*, January 2004, Vol. 23, pp36-48) as applied to claims 1 and 25 above, and further in view of Dieffenbach (U.S. Patent No. 5,089,421, Feb. 18, 1992) (hereinafter "Dieffenbach").

Gumbrecht in view of Blanco-López teaches a sensor and method of detecting target species in a sample using the sensor as set forth above. However, Gumbrecht in view of Blanco-López is silent on teaching that the sample is returned to the patient.

Dieffenbach teaches an apparatus of for analyzing blood, which allows collection, analysis, and return of a blood sample of a patient without the sample being exposed to ambient air (see entire document, particularly column 2, lines 4-21). Such apparatus is

Art Unit: 1641

useful for the continuous monitoring of arterial blood in neonates or adults (column 1, lines 15-17).

Therefore, it would have been *prima facie* obvious to one of ordinary skill in the art at the time of the invention to employ the blood collection apparatus of Dieffenbach in the sensor of Gumbrecht in view of Blanco-López in order to allow continuous blood analysis. The advantage of allowing collection, analysis, and return of a blood sample of a patient without the sample being exposed to ambient air provides the motivation to combine teachings of Gumbrecht in view of Blanco-López and Dieffenbach with a reasonable expectation of success.

Conclusion

17. No claim is allowed.

18. Any inquiry concerning this communication or earlier communications from the examiner should be directed to UNSU JUNG whose telephone number is (571)272-8506. The examiner can normally be reached on M-F: 9-5.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Mark Shibuya can be reached on 571-272-0806. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Art Unit: 1641

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Unsu Jung/
Unsu Jung
Primary Examiner
Art Unit 1641